MISSOURI BOARD OF PHARMACY

NEWSLETTER

SEPTEMBER 2019

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NEW BOARD OFFICERS

DOUGLAS LANG

Douglas Lang, RPh., was elected President of the Board in July 2019. President Lang received his Bachelor of Science degree in 1981 from the Saint Louis College of Pharmacy. He holds licensure as a pharmacist in Arkansas, Delaware Louisiana, and Nebraska. Mr. Lang started his phar-macy career at Saint Louis University Medical Center serving as a Staff Pharmacist and Assistant Director of Pharmacy. He then practiced in the area of Home Infusion Pharmacy for over fifteen years and was the Pharmacy Manager of the BJC Home Infusion Program. Currently, Mr. Lang is the Vice President of Pharmacy Compliance for Express Scripts Inc., based in St. Louis, Missouri. He provides compliance oversight to the company's mail-order, specialty, fertility pharmacies and its specialty drug distribution operations. He is a member of the Saint Louis Society of Health System Pharmacists, the Missouri Society of Health System Pharmacists, the American Society of Health-System Pharmacists and the National Association of Boards of Pharmacy. He is a past recipient of the Saint Louis Society and Missouri Society

Pharmacist of the Year Award and a past recipient of the Missouri Research and Education Foundations Thomas Garrison Award. He is a past member of the Missouri Board of Pharma-cy serving from 2002 to 2007.

JAMES L. GRAY

James L. Gray III, PharmD, MBA, was also elected to serve as Board Vice-President in July 2019. Mr. Gray is currently Executive Director of Pharmacy at Barnes-Jewish Hospital, a position he has held since 1983. From 1988 to 1995, Dr. Gray also served as the administrative director for transplant programs at Barnes-Jewish Hospital. From 1979 to 1983, Dr. Gray held clinical and administrative positions at LifeMark Pharmacy Management in Houston, TX and from 1977 to 1979 was an assistant professor at the Ohio State University College of Pharmacy. Dr. Gray received a BS in pharmacy from the University of Pittsburgh in 1975. He earned a PharmD at Duquesne University and completed an ASHP accredited residency in pharmacy practice at Mercy Hospital, Pittsburgh, in 1977. He completed his MBA at Washington University in 2001. He is a member of the American Society of Health-System Pharmacists, Missouri Society of Health System Pharmacists, Missouri Pharmacy Association and National Association of Boards of Pharmacy. He is a past recipient of the Missouri Society of Health System Pharmacists Research and Education Foundation's Thomas J. Garrison Achievement Award and previously served on the Board from 1997 to 2002.

DEPARTMENT NAME CHANGE

The Board of Pharmacy was previously housed within the Missouri Department of Insurance, Financial Institutions and Professional Registration (DIFP). Effective August 28, 2019, DIFP was renamed the Department of Commerce and Insurance (DCI). The name change came as part of Governor Mike Parson's initiative to improve economic and workforce development in Missouri.

DCI staff have worked tirelessly to ensure a seamless transition. The Board's physical address and all Board e-mail addresses and phone numbers will remain the same, however, licensees will see a new logo!

DCI
Missouri Department of Commerce & Insurance

2019 LEGISLATIVE UPDATE

The 2019 legislative session has officially ended. Several pieces of pharmacy legislation were enacted this year that *became effective on August 28, 2019*. The following legislative summary is being provided for informational purposes. The summary includes several key pharmacy bills but is not a comprehensive review of all new legislation. Licensees should independently review statutory changes to ensure compliance. Statutory changes to Chapter 338, RSMo, are available in the official online version of the Revised Statutes of Missouri and also on the Board's website.

NICOTINE REPLACEMENT THERAPY

Section 338.010.1 was amended to grant pharmacists authority to prescribe a prescription or over-the-counter "nicotine replacement therapy product." A "nicotine replacement therapy product" is defined in newly enacted § 338.665 as:

> *Any drug or product, regardless of whether it is available over-the-counter, that delivers small doses of nicotine to a person and that is approved by the federal Food and Drug Administration for the sole purpose of aiding in tobacco cessation or smoking cessation.*

This definition would include nicotine gum, patches, lozenges, nasal spray and inhalers. According to currently approved FDA labeling, Zyban® and Chantix® do not contain nicotine and would therefore not constitute a "nicotine replacement therapy product" as defined by § 338.665.

Under the new law, pharmacists can independently prescribe a nicotine replacement therapy product. A physician protocol or collaborative practice agreement is **not** required. Instead, the pharmacist would be the official prescriber of record and prescriptions under § 338.665 may be transmitted to/filled by another pharmacy for dispensing.

Although the new law became effective August 28, 2019, the Board is required to promulgate rules in conjunction with the Missouri Board of Registration for the Healing Arts to implement the new allowance. Pharmacists cannot begin prescribing nicotine replacement therapy products until the required joint rules are finalized. The Board has prioritized this rule and reviewed potential rule language during its August 2019 meeting. The Board anticipates having a rule draft rule available for review by the Board of Healing Arts in the fall. Interested parties should monitor the Board's website and e-alerts for future rule developments.

MANDATORY E-PRESCRIBING OF CONTROLLED SUBSTANCES

Section 195.550, RSMo, was amended to mandate electronic prescribing of C-II to C-IV controlled substances, beginning January 1, 2021. The new law contains multiple exceptions including:

(1) Prescriptions issued by veterinarians,

(2) If electronic prescribing is not available due to temporary technological or electrical failure,

(3) Entities granted a waiver by the Missouri Department of Health and Senior Services due to economic hardship, technological limitations or other exceptional circumstances,

(4) If the prescriber reasonably determines that it would be impractical for the patient to fill an e-prescription in a timely manner, and the delay would adversely impact the patient's medical condition, or

(5) If the patient specifically requests a written prescription. [See § 195.550 for all exceptions]

The new provisions will be regulated by BNDD who will be issuing additional guidance in the future. In the interim, interested parties should review § 195.550 and also review the Board's 2018 Legislative Update webinar recording which included a general presentation from BNDD on the new provisions.

CONTROLLED SUBSTANCE PRESCRIBING LIMITS

Section 195.080 provides that initial opioid prescriptions for acute pain cannot exceed a seven (7) day supply. Section 195.080.2 contains exemptions to the supply limit for patients undergoing cancer treatment, patients receiving hospice or palliative care from a certified hospice under Chapter 197, RSMo, long-term care residents or patients receiving substance abuse or opioid dependence treatment.

In 2019, § 195.080.2 was amended to also exempt patients undergoing treatment for sickle cell disease from the seven (7) day supply limit. Once again, the new law became effective on August 28, 2019 and is applicable now.

PHARMACY PILOT PROJECTS

The Board has been asked to consider a variety of technology or remote dispensing projects over the years. Many times, little or insufficient data existed to assist the Board in identifying the best regulatory approach or assessing potential impact on patient safety or access to care. Section § 338.143, RSMo was recently enacted which granted the Board authority to approve pharmacy pilot or demonstration research projects related to technology assisted verification or remote medication dispensing. The new law will assist the Board in gathering Missouri-specific data to support future regulatory and legislative proposals.

Applications to operate a pilot or demonstration research project are currently being accepted by the Board. Individuals/entities with a current and active Board license, permit or registration are eligible to apply.

An informational FAQ is available on the Board's website along with a sample application and a copy of emergency rule 20 CSR 2220-2.995 which was recently filed to implement the new law.

RX CARES FOR MISSOURI MEDICATION DESTRUCTION AND DISPOSAL PROGRAM

In 2017, the Missouri General Assembly enacted § 338.142, RSMo, which gave the Board authority to establish a drug take-back program for controlled substances. The Board subsequently promulgated Rule 20 CSR 2220-2.900 which established the Rx Cares for Missouri Medication Destruction and Disposal Program (the "Program"). Under the Program, the Board will provide resources to approved participants for collecting unused/unwanted medication from the public for disposal.

The Board is pleased to announce that Program enrollment is now open! The Program will be operated by the Board's contracted vendor, Sharps Compliance, Inc. (Sharps), as part of Sharps' Medsafe® drug collection/disposal initiative.

Approved Program participants will be required to enroll in Medsafe®. After enrollment, Program participants will be provided a Medsafe® controlled substance collection receptacle at no cost along with approved inner liners for collecting unused/unwanted medication from the public. The Board will also provide funding for destroying/disposing of collection medication through the Medsafe® program up to twelve (12) times during the participation period.

To participate, interested applicants must file an application with the Board and be approved. Limited funding is available so applicants are encouraged to apply early. The following entities are eligible to apply:

- A licensed Missouri pharmacy or drug distributor
- A hospital/clinic with an onsite pharmacy
- A narcotic treatment program, or
- A federal, state, tribal or local law enforcement agency (collection receptacles must be located inside the law enforcement agency's physical address). [See rule 20 CSR 2220-2.900 for additional eligibility information]

Additionally, applicants must be **currently** registered with the DEA and BNDD as an authorized collector of controlled substances (law enforcement agencies are not required to be registered). Once approved, Participants will be responsible for operating a medication collection program in compliance with state and federal controlled substance laws.

A **Rx Cares Informational Guide** and an Application Packet are available on the Board's website. The **Informational Guide** contains detailed information on Program operations and Medsafe®. Once again, funding is limited. As a result, applications are requested before October 1, 2019.

The Board is excited to provide this opportunity as we continue to combat the opioid crisis.

A NOTE ON MEDICAL MARIJUANA

The Missouri constitution was amended in 2018 to allow the use of medical marijuana pursuant to rules promulgated by the Missouri Department of Health and Senior Services (DHSS). DHSS has established an online information portal which includes updates on medical marijuana regulation at https://health.mo.gov/safety/medical-marijuana/index.php.

Licensees should contact DHSS with questions on medical marijuana or the new law. The Board does not have jurisdiction over the new provisions and cannot answer questions or provide guidance.

Please note the Board has received multiple questions from licensees asking if pharmacists can own, advise or consult with a medical marijuana dispensary/cultivator. Licensees should consult with legal counsel on this issue- the Board cannot provide legal advice. However, the DEA had advised that federal controlled substance registrants are required to comply with federal law which still designates marijuana as a C-I controlled substance.

The Board is aware that medical marijuana companies are heavily soliciting Missouri pharmacists at this time. The Board cautions licensees to thoroughly research companies to ensure the entity is in compliance with state law.

PHARMACY REMODELING QUESTIONS ANSWERED

See the below guidance on commonly asked questions regarding pharmacy remodeling:

What is the difference between a remodel and a change of location? A remodel involves modifications within the existing structure. A change of location is a move out of the current structure to a different structure.

What constitutes a remodel? 20 CSR 2220-2.020 defines remodeling as:

- Any change in the storage conditions of Schedule II substances (this includes adding new storage or relocating existing),
- Any new connections to water/sewer resources (this includes relocating an existing sink), or
- Any changes in the overall physical security of drugs stored in the pharmacy (this can including acquiring additional pharmacy space).

Who should I contact if I am unsure if my modifications are a remodel? Your inspector is familiar with your pharmacy and would be the best person to contact.

Do I need to submit an application for a remodel? No, however, if your modifications meet the regulation's definition you must notify the Board 30 days prior to the start. Additionally, the pharmacy has to submit an affidavit that includes a description of the proposed changes and the projected completion date. The required affidavit may be sent to the Board office or to your inspector.

Do I need to submit official blueprints? No, but you are required to submit a diagram of the changes. This can be a rough sketch instead of blueprints.

Does a remodel require an inspection? No. Your inspector will review the submission and will contact you with questions, if needed. Your inspector will notify you if your submission is approved.

What questions might an inspector have? Your inspector may need clarification on your submission, such as, where the sink or the Schedule II storage area will be located or if the walls extend above the ceiling with no open access points.

Are hospitals required to notify the Board of remodels? Yes, if the hospital pharmacy is licensed with the Board and the modifications meet the regulation's definition. This applies even if the activity occurring within the licensed pharmacy is regulated by the DHSS.

Important DHSS Information on ShowMeVax

This information has been provided by the Missouri Dept. of Health and Senior Service. Questions should be addressed to DHSS as indicated below

The Department of Health and Senior Services (DHSS) continues to progress through the project steps to replace the ShowMeVax Immunization Information System (IIS) with a new system. DHSS will be converting to a new ShowMeVax system which will go live in January 2020.

Pharmacies with existing interfaces will need to work with their technology vendor to switch the interface to the new system after it is rolled out. Those with manual entry access will need to create an account in the new system and will have access to training. DHSS will be on hand to facilitate the changeover for all our users.

Please visit DHSS' project website for updates and frequently asked questions at www.health.mo.gov/iisupgrade. For questions related to the project, contact the ShowMeVax Helpdesk at showmevaxsupport@health.mo.gov or 877-813-0933.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS - 2ND QUARTER 2019

(The following information was provided by the National Association of Boards of Pharmacy and is reprinted with permission of NABP. This information is provided for informational purposes only and does not express or represent the views or opinions of the Missouri Board of Pharmacy.)

FDA CHANGES OPIOID LABELING TO GIVE PROVIDERS BETTER INFORMATION ON TAPERING

Noting that the agency remains focused on striking the right balance between policies that reduce the rates of opioid addiction while still allowing patients and health care providers access to appropriate pain treatments, Food and Drug Administration (FDA) has announced required changes to the prescribing information for all opioid analgesic medications used in the outpatient setting. The changes, announced in a Drug Safety Communication, provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. FDA intends for this information to be used when health care providers and patients have decided together that a decrease in dose or discontinuation of opioids is appropriate.

"Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse," the agency said in the communication. "Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances."

In addition to these changes, an FDA press release also announced that additional policies related to the opioid crisis are forthcoming. These include a requirement for immediate-release formulations of opioids to be made available in fixed-quantity packaging that contain doses more typical of what patients may need for common acute pain conditions and procedures. The full press release is available at https://www.fda.gov/news-events/press-announcements/statement-douglas-throckmorton-md-deputy-center-director-regulatory-programs-fdas-center-drug-0.

DEA WARNS OF SCAM CALLS TARGETING PHARMACISTS AND OTHER DEA-REGISTERED PROVIDERS

Health care providers and other members of the public have reported receiving phone calls from people claiming to represent Drug Enforcement Administration (DEA), and threatening legal action against them if a large fine is not paid immediately over the phone. According to a DEA press release, this scam used fake names and badge numbers, or the names of well-known senior officials with DEA, and threatened victims with arrest, prosecution, imprisonment, and revocation of their DEA numbers. The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of legitimate investigation or legal action is made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

FDA OFFICIALS OUTLINE 2019 EFFORTS TO IMPROVE QUALITY OF COMPOUNDED DRUGS

Recognizing the important roles compounded drugs can play in patient care, Food and Drug Administration (FDA) plans to continue its efforts to improve the quality of compounded drugs. According to a statement posted to the FDA website, these priorities include:

- Maintaining quality manufacturing compliance,
- Strengthening and refining regulations on compounding from bulk drug substances,
- Finalizing the agency's memorandum of understanding with the states, and
- Issuing revised draft guidance for compounding by hospital and health systems.

"We've worked to refine our existing practices, shape new policies, and increase the frequency of our communications with industry, Congress, states, and patients concerning our programs," then-Commissioner Scott Gottlieb, MD, and Deputy Commissioner Anna Abram said in a statement published on the FDA website. "We anticipate that 2019 will be an equally productive year for the FDA's compounding program, with better

quality continuing to be our top priority as part of our ongoing effort to improve the quality of compounded products for consumers ...."

In addition, Gottlieb and Abram's statement notes that the agency will continue to work closely with stakeholders on these steps and any other compounding-related measures not outlined in the statement.

CHINA AGREES TO STRICTER FENTANYL PRODUCTION LAWS FOLLOWING PRESSURE FROM US LAWMAKERS

China has announced that all variations of the powerful opioid product, fentanyl, will be treated as controlled substances (CS). According to a press release from Senator Tom Cotton, the announcement came after a bipartisan group of United States lawmakers, including Cotton, introduced Senate Bill 1044, a bill designed to apply pressure to the Chinese government to make all forms of synthetic opioids illegal and to provide US law enforcement with more tools and resources to go after illicit traffickers in China, Mexico, and other countries.

"Combating the flow of illicit fentanyl into our country is imperative in the fight to save American lives from the opioid crisis," Senate Minority Leader Chuck Schumer said in the press release. "We must hold China accountable for their role in the fentanyl trade. China's new regulation to make all fentanyl categories illegal is an important step and the administration deserves praise for their efforts to secure this change. However, we have to demonstrate that we will demand China enforce these laws and take strong action against opioid traffickers."

In a December meeting with President Trump, China's President Xi Jinping promised to classify fentanyl as a CS following a 2018 report by the US-China Economic and Security Review Commission that found China to be "the largest source of illicit fentanyl and fentanyl-like substances" in the US, according to a report from NPR. The latest increase in opioid-related overdose deaths have been largely attributed to the availability of illegally manufactured fentanyl.

TWO LOTS OF TRANSDERMAL FENTANYL PATCHES RECALLED DUE TO PRODUCT MISLABELING

Alvogen, Inc, of Pine Brook, NJ, is recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level after a small number of cartons were found to contain 50 mcg/h patches. Though the 50 mcg/h patches are individually labeled correctly, accidental application of the higher dosage patch instead of the prescribed 12 mcg/h patch could result in serious, life threatening, or fatal respiratory depression. The company has not received any reports of adverse events related to this issue.

The company is notifying its distributors and direct customers by certified letter and is arranging for the return and replacement of all recalled products. Pharmacies are asked to stop dispensing any product subject to the recall. Consumers that have affected products should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to the point of purchase for replacement.

Additional information on the recall, including the affected lot numbers and customer service contact information is available in a press release posted to the FDA website at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/alvogen-inc-issues-voluntary-nationwide-recall-fentanyl-transdermal-system-due-product-mislabeling. Adverse reactions and quality problems can be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

FDA RELEASES TOOLKIT TO HELP PROMOTE SAFE OPIOID DISPOSAL

Food and Drug Administration (FDA) has made a new resource available for consumers and health care providers to help promote and educate individuals about how to safely dispose of unused opioids. The free Safe Opioid Disposal – Remove the Risk Outreach Toolkit includes video, radio, and print public service announcements, social media graphics and posts, fact sheets, drop-in content, and website badges that health care providers and other interested individuals and organizations can use to promote the message of opioid safety. The toolkit and its resources can be accessed on the Ensuring Safe Use of Medicine section of the FDA website.

An additional resource available to help consumers find disposal kiosks available year-round is NABP's Drug Disposal Locator Tool, available in the AWARXE® Prescription Drug Safety section of the NABP website, www.nabp.pharmacy/initiatives/AWARxE. With more than 6,500 disposal sites in the continually updated database, consumers can enter location information to find the nearest disposal sites to them using a map. Additional information about the campaign at https://www.fda.gov/drugs/buying-using-medicine-safely/ensuring-safe-use-medicine.